DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Rockville MD 20857

DEC 9 1998

NDA 11 -870/S-031
NDA 11-145/S-085

Merck & Co., Inc.
Attention: Jeffery R. White, M.D.
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. White:

Please refer to your supplemental new drug applications dated December 3, 1996 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diuril (chlorothiazide) Tablets (NDA 11-145) and Oral Suspension (NDA 11-870).

We acknowledge receipt of your submission dated September 22,1998.

These supplemental new drug applications provide for final printed labeling revised by adding information relating to the dosing of this product in the pediatric population as required in the December 13, 1994 Federal Register notice entitled: "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of 'Pediatric Use' subsection in the Labeling."

The following revisions were made:

1. The PRECAUTIONS/Pediatric Use subsection was changed from:

   Safety and effectiveness in children have not been established.

to:

There are no well-controlled clinical trials in pediatric patients. Information on dosing in this age group is supported by evidence from empiric use in pediatric patients and published literature regarding the treatment of hypertension in such patients. (See DOSAGE AND ADMINISTRATION, Infants and Children).

2. Under DOSAGE AND ADMINISTRATION/Infants and Children/For Diuresis and For Control of Hypertension subsection, "pediatric patients" was changed to "children" in the first sentence and "(See PRECAUTIONS, Pediatric Use)" was added to the end of the section.

3. Under DOSAGE AND ADMINISTRATION, the subsection "Pediatric Patients/For Diuresis and For Control of Hypertension" was replaced with "Infants and Children/For Diuresis and For Control of Hypertension."

We also note that the following additional changes were made to the HOW SUPPLIED section:

1. "(6505-01-156-1600, 250 mg/5mL, 237 ml)" was added as the last line.

2. The 1,000 count bottle of 250 mg strength was deleted; this size is no longer available.

3. The 1,000 and 5,000 count bottles of the 500 mg strength was deleted; these sizes are no longer available.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert included in your September 22,1998 submission). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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